Protocol for the Feasibility Study of INSPIRE: an Individually Tailored Support Intervention for Informal Caregivers of Older Adults With Rheumatoid Arthritis and Frailty

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Trial registration: The study will be registered in a publicly accessible trial registry (e.g., ClinicalTrials.gov or ISRCTN) before recruitment begins. Registration ID will be added once available

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Abstract

Background: Rheumatoid arthritis (RA) is a chronic inflammatory disease associated with pain, fatigue, functional limitations, and reduced quality of life. As more people live to older age with RA, age-related vulnerability such as frailty becomes increasingly relevant and may amplify functional decline, multimorbidity, and reliance on others. Informal caregivers (unpaid family members, friends, or neighbors) often provide substantial practical, emotional, and coordination support, yet caregiver needs are frequently overlooked in rheumatology care. INSPIRE (INtervention to Support Partners and Informal caREgivers of frail patients with RA) is an individually tailored support intervention developed using the UK Medical Research Council framework for complex interventions and an iterative co-creation process involving older adults with RA and frailty, caregivers, healthcare professionals, and social care stakeholders. Before a definitive evaluation, feasibility and acceptability in routine care must be established.

Aim: To evaluate the feasibility and acceptability of delivering INSPIRE in routine rheumatology care and to test study procedures in preparation for a future definitive trial.

Methods: This is a single-arm feasibility study recruiting 25 informal caregivers of older adults with RA and frailty. Recruitment will occur within a fixed four-month window (1 March–1 July 2026) and will not be extended. Care recipients (older adults) will be ≥65 years with RA and frailty classified as Clinical Frailty Scale (CFS) 4–7. Caregivers will be ≥18 years, provide unpaid support, and report at least moderate burden defined as a Caregiver Burden Scale (CBS) mean score >1.99 at screening. Participants will be recruited from Rigshospitalet (Center for Rheumatology and Spine Diseases) and rheumatology departments in Køge, Slagelse, and Holbæk. Identification uses routine patient-reported outcomes (DANBIO) with invitation of potentially frail patients (e.g., MDHAQ >1.0) followed by telephone screening and CFS assessment; eligible patients nominate a caregiver who is then screened using CBS.

Intervention: INSPIRE is delivered by a trained healthcare professional over ~12 weeks and comprises three contacts: an initial consultation (60–90 min), a brief follow-up (15–30 min), and a final consultation (30–60 min). Content is tailored using a toolbox addressing validation of the caregiver role, emotional/practical support, education, communication, and navigation across health and municipal services. Involvement of the older adult in consultations is optional and based on preferences of both parties.

Outcomes: Feasibility outcomes include recruitment (screened/eligible/consented), retention at 12 weeks, questionnaire completeness, and deliverability (session completion, mode, duration). Acceptability will be assessed post-intervention using brief acceptability/feasibility questions and qualitative interviews with informal caregiver. Fidelity and tailoring will be documented using structured session notes. Exploratory outcomes include Care burden (CBS), quality of life (WHOQOL-BREF) (informal caregiver and older adult), and physical function (MDHAQ).

Progression criteria: Pre-specified criteria include approximately 50% recruitment of those approached, ≥85% retention, and high fidelity, reviewed using a traffic-light approach (go/amend/stop).

Ethics and dissemination: Written informed consent will be obtained from both the older adult and the informal caregiver prior to baseline data collection, with separate consent for any study components each participant takes part in (e.g., consultations, interviews). Findings will be disseminated through peer-reviewed publication, conferences, stakeholder summaries and patient organizations.

Trial registration: The study will be registered in a publicly accessible registry (e.g., ClinicalTrials.gov or ISRCTN) prior to recruitment; the registration ID will be added when available.

Background

Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease that primarily affects the joints and is associated with pain, stiffness, swelling, reduced function, and fatigue, and it can also affect other organs and overall well-being [1,2] . Mental health problems are common in RA; depression in particular is associated with higher pain and disability and lower health-related quality of life [3,4]. As more people live longer with RA, an increasing proportion of patients reach older age, where age-related vulnerability such as frailty becomes more relevant; epidemiological data show that RA burden and occurrence increase with age [5].

Frailty is commonly described as a state of increased vulnerability to stressors due to reduced physiological reserve across multiple systems, which increases the risk of adverse outcomes and fluctuating functional capacity [6]. In community-dwelling older adults, frailty is prevalent, with estimates varying by definition and setting but consistently demonstrating that a substantial proportion of adults aged 65 years and older are affected [7]. In older adults living with both RA and frailty, functional decline and multimorbidity can increase reliance on others in daily life.

In this context, informal caregivers (unpaid family members, friends, or neighbors) often become central contributors to everyday disease management, including practical support, coordination, and treatment/medication-related tasks [8]. Health systems also increasingly depend on the capacity of patients and families to manage chronic illness in the community; evidence shows that family caregivers are linked with fewer and shorter hospital stays for older adults, illustrating the system-level importance of caregiving contributions [9]. However, these responsibilities can place substantial emotional and practical demands on caregivers.

These demands may lead to caregiver burden, a multidimensional strain encompassing emotional, physical, social, and financial aspects of providing care [10]. Caregiver burden is associated with adverse caregiver outcomes, including distress and reduced health and quality of life, and it is often overlooked in clinical practice [11]. Although interventions for caregivers in other chronic disease populations suggest that psychosocial and educational support can reduce distress and burden and improve quality of life, structured caregiver support remains limited in rheumatology care and is rarely implemented systematically for caregivers of older adults with RA and frailty [12].

INSPIRE (INtervention to Support Partners and Informal caREgivers of frail RA patients) was developed using the UK Medical Research Council (MRC) framework for complex interventions (REF) and an iterative co-creation process involving older adults with RA and frailty, informal caregivers, healthcare professionals, and social care stakeholders. INSPIRE is designed to recognize and validate the caregiver role, provide emotional and practical support, and facilitate navigation and coordination across fragmented services through a tailored "toolbox" delivered by trained healthcare professionals over approximately twelve weeks. Before evaluating effectiveness, a feasibility study is required to assess recruitment, acceptability, delivery, and data collection procedures in routine clinical practice.

Aim and objectives

The overall aim is to evaluate the feasibility and acceptability of delivering INSPIRE in routine rheumatology care and to test study procedures for a future definitive evaluation.

Comprising the feasibility of:

- Identifying and recruiting eligible caregiver participants, retaining participants through follow-up, collecting outcome data with acceptable completeness, and delivering the intervention as intended

Explore:

- Perceived usefulness of the intervention, acceptability of the intervention, Implementation barriers and facilitators among:
    - Caregivers
    - Older adults
    - Intervention-delivering professionals

Provide preliminary estimates of outcome variability to inform:

- Selection of outcomes for a subsequent trial and sample size planning for a subsequent trial

Progression criteria

Progression to a definitive evaluation will depend on whether recruitment and retention are adequate; whether the intervention can be delivered as intended within routine practice; whether outcome measures are acceptable and sufficiently complete; and whether participants and healthcare professionals consider INSPIRE relevant and acceptable. Pre-specified thresholds (e.g., minimum consent and follow-up rates) will be agreed and reviewed with stakeholders.

Methods

Study design

This study is a feasibility study designed to assess whether INSPIRE and the planned trial procedures are deliverable and acceptable This study is designed to evaluate progression criteria in preparation for a full-scale RCT and to identify areas where adjustments of the intervention and/or study design were needed. Our progression criteria include a 50% recruitment rate of all patients approached, an 85% retention rate, and overall high fidelity.

Study setting

The study will be conducted at the Center for Rheumatology and Spine Diseases, Rigshospitalet (Denmark), with intervention delivery across the Capital Region and Region Zealand. Consultations will take place in the outpatient clinic, in caregivers' homes, and/or by telephone according to informal caregivers preference and feasibility.

Recruitment window and stopping rule

Recruitment will take place within a fixed four-month window from 1 March to 1 July 2026 and will not be extended. If the planned sample size is not reached by 1 July, recruitment will nonetheless stop at the end of the recruitment window, and the study will proceed with participants already enrolled (including completion of follow-up).

Participants and eligibility

The primary participants are informal caregivers of older adults with RA and frailty. Informal caregivers will be eligible if they are aged ≥ 18 years, provide unpaid support to an older adult aged ≥ 65 years with a confirmed RA diagnosis, and are able to provide informed consent and complete study questionnaires. Informal caregivers must report at least moderate burden, defined as a mean score above 1.99 on the Caregiver Burden Scale (CBS) at screening.

The care recipient must meet a pre-specified frailty criterion assessed in routine care, by the Clinical Frailty Scale (CFS), with eligibility defined as CFS 5 or higher. Older adults with RA and frailty are not the primary intervention recipients but may be involved in selected consultations if both parties believe it is relevant. Separate consent will be obtained from older adults for any involvement and for any linkage of clinical information. The care recipient must consent to the primary participants (informal caregiver) participation.

Informal caregivers will be excluded if participation is not possible due to severe cognitive impairment, acute mental health crisis, or other circumstances that make it impracticable to complete the intervention and follow-up.

Sample size

This study is a feasibility study designed to assess whether INSPIRE and the planned trial procedures are deliverable and acceptable, rather than to test effectiveness. In line with CONSORT guidance for pilot and feasibility trials and NIHR guidance [13,14], a formal power calculation based on clinical outcomes is therefore not appropriate; instead, the sample size is chosen to provide sufficiently informative estimates of key feasibility parameters (recruitment, retention, and intervention delivery/fidelity) and to identify areas requiring modification before a full-scale RCT.

We will aim to include 25 informal caregivers in this single-arm feasibility study within the fixed recruitment window. This sample size is considered adequate for evaluating our progression criteria and informing decisions using a traffic-light approach (go/amend/stop), as recommended for feasibility work [15,16]. With a target recruitment rate of 50% of those approached, enrolling 25 participants corresponds to approaching approximately 50 eligible caregivers during the recruitment period. If

25/50 are recruited (50%), the 95% confidence interval for the recruitment proportion is expected to be approximately 0.37 to 0.63, which is sufficiently precise to detect clearly inadequate recruitment (e.g., around 30% or lower) and to guide procedural amendments if needed [13,17].

For retention, with 25 enrolled and a progression target of 85%, we would expect approximately 21–22 participants to complete follow-up. The corresponding 95% confidence interval around an observed retention proportion close to this target remains informative for feasibility decision-making (e.g., for 21/25, ~0.65–0.94; for 22/25, ~0.70–0.96), and the combination of quantitative retention estimates with qualitative feedback will allow us to determine whether any loss to follow-up is acceptable and modifiable before scaling to a definitive RCT [17,18].

Finally, the sample provides sufficient exposure to assess intervention delivery and fidelity in practice. As INSPIRE includes three consultations over 12 weeks, inclusion of 25 caregivers will generate approximately 75 intervention contacts, enabling structured fidelity documentation, identification of implementation challenges, and refinement of training and materials, which is the central purpose of feasibility evaluation [15]. In addition, a sample of this size is consistent with common feasibility study targets reported in reviews of pilot and feasibility studies and is appropriate for informing a subsequent definitive trial [13,17].

Recruitment

Informal caregivers of older adults diagnosed with RA will be recruited from the Department of Rheumatology and Spine Diseases at Rigshospitalet, Denmark, and the Departments of Rheumatology in Køge, Slagelse, and Holbæk. Eligible patients (care recipients) will be aged ≥65 years and classified as frail with a Clinical Frailty Scale (CFS) score of 4–7.

Patients with RA are routinely invited to complete patient-reported outcomes in the Danish National Clinical Rheumatology Registry (DANBIO) [19] prior to outpatient visits. Frailty is not currently assessed in DANBIO; however, the Multidimensional Health Assessment Questionnaire (MDHAQ), which captures functional ability, disability, and capacity to perform activities of daily living, is included. MDHAQ scores are known to correlate with frailty [20]. A score of ≥1.3 on the Health Assessment Questionnaire Disability Index (HAQ-DI) has been shown to correspond to very mild frailty, and HAQ-DI can be

converted to an MDHAQ score using the algorithm: MDHAQ = (HAQ-DI/1.08) − 0.15 [21,22]. On this basis, all patients aged ≥65 years with RA attending the participating departments between March and August 2026 who score >1.0 on the MDHAQ will be invited to receive additional information about the study. The invitation will appear as a pop-up at the screen when patients complete the DANBIO questionnaires, allowing them to indicate interest (yes/no) in the INSPIRE project.

Patients who indicate interest will receive detailed written information and will subsequently be contacted by telephone by a member of the study team to receive verbal information and to address any questions. Eligibility will then be assessed using the CFS to determine frailty status. The CFS is a widely used and well-validated instrument in both international research and Danish clinical practice [23,24]. CFS evaluates domains including comorbidity, function, and cognition to generate a frailty score ranging from 1 (very fit) to 9 (terminally ill) [23]. We selected the CFS range 4–7 to capture variation in frailty, from very mild frailty (CFS 4) to severe frailty (CFS 7).

If a patient meets the eligibility criteria (CFS 4–7, age ≥65 years, and RA diagnosis), the study team will ask the patient to identify an informal caregiver (e.g., spouse/partner, family member, or close friend). The informal caregiver will be contacted by the study team and provided with written information about the study. Caregivers who express interest will be screened using the CBS to confirm eligibility. Caregivers should have a CBS score indicating moderate or greater burden. See Figure 1 for recruitment flow.

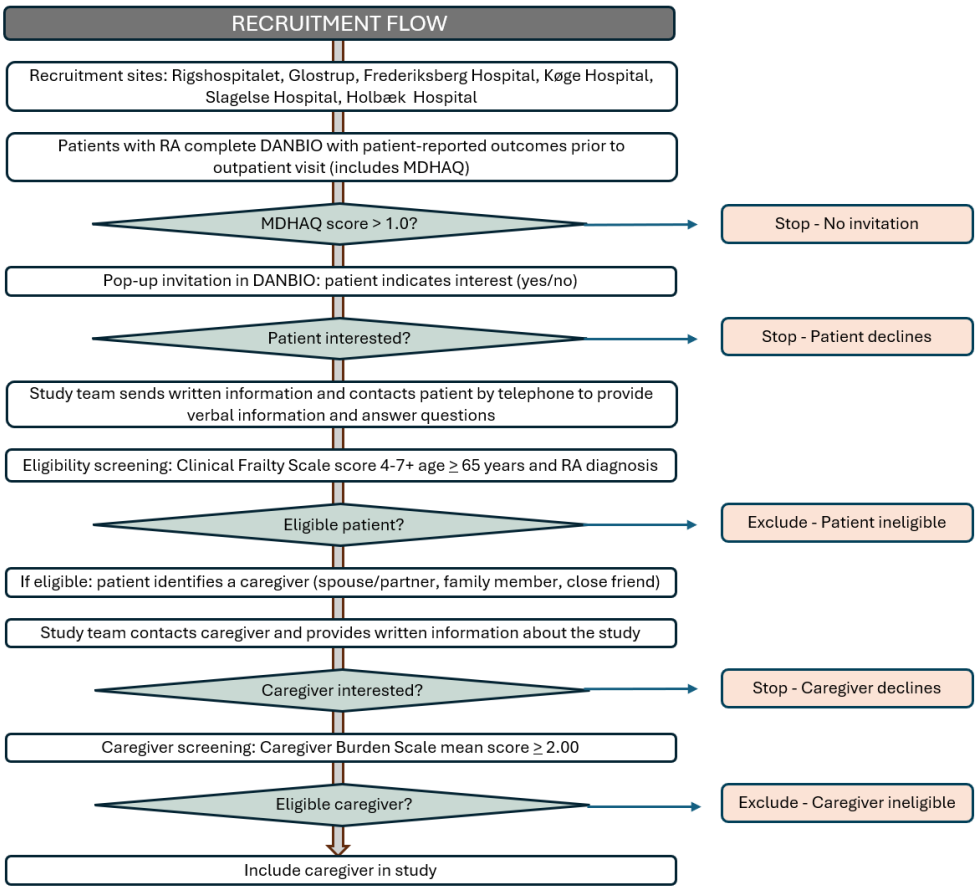

Figure 1. Flow chart

Consent procedures

Written informed consent will be obtained from both the older adult with RA and the informal caregiver prior to baseline data collection Each participant (older adult and informal caregiver) will provide their own consent.

Intervention

INSPIRE is delivered by a trained healthcare professional with rheumatology expertise and experience in psychosocial support and service navigation. The intervention runs over approximately twelve weeks and includes an initial consultation, follow-up, and a final consultation. The initial consultation (about 60–90 minutes) takes place at home or in the clinic and is guided by the caregiver's CBS profile.

The consultation focuses on recognizing and validating the caregiver role, identifying the most burdensome issues, exploring underlying causes, and establishing realistic goals. Based on the needs identified, the informal caregiver is introduced to a tailored toolbox of resources and referral pathways that may include emotional or psychological support options, guidance on managing practical and physical strain, support for social isolation, communication and relationship support, disease-related education, and assistance navigating municipal and health system services such as home care, assistive devices, or case management.

The second consultation is a brief follow-up contact (typically by phone, about 15–30 minutes) and used to review progress and adjust goals and support plans together with informal caregiver.

The final consultation (about 30–60 minutes, phone or face-to-face) takes place within twelve weeks and focuses on evaluating the intervention experience, reviewing outcomes, and planning any ongoing support needs. Involvement of the older adult is optional and can be included in later consultations when considered relevant and desired by both informal caregiver and older adult.

Outcomes and data collection

Feasibility outcomes will describe recruitment (screened, eligible, consented) within the fixed recruitment window, retention at 12 weeks, completeness of questionnaire data, and the practicality of delivering INSPIRE (session completion, delivery mode, and session duration).

Acceptability will be assessed using brief post-intervention acceptability questions and qualitative interviews.

Fidelity and tailoring will be documented using structured session notes indicating whether core components were delivered, and which toolbox elements were selected.

Caregiver burden will be measured using the CBS. The CBS is a 22-item self-report questionnaire covering five domains (general strain, isolation, disappointment, emotional involvement, and environment) with responses typically scored on a 4-point scale; higher scores indicate higher perceived burden [26,27]. The CBS has demonstrated validity and reliability in its original development [26], and the

Danish version has shown good internal consistency (total scale Cronbach's alpha around 0.93) without marked floor/ceiling effects, supporting its use for caregiver populations in Denmark [28].

Quality of life will be measured using WHOQOL (World Health Organization Quality of Life) for both caregivers and patients (older adults with RA and frailty), using the WHOQOL-BREF (brief) format. WHOQOL-BREF is a 26-item generic quality-of-life instrument covering four domains (physical, psychological, social relationships, and environment) plus overall QoL/general health items, developed by the World Health Organization for cross-cultural use [29]. Psychometric evaluations have shown good to excellent reliability and evidence of validity across field trials and settings [29], and the Danish translation has been evaluated and found psychometrically acceptable, supporting its use in Danish samples [30]. Each item is rated on a 5-point Likert scale with values ranging from 1 to 5 (minimum = 1; maximum = 5). Higher scores indicate better quality of life / better perceived health. Domain scores are typically calculated by summing relevant items and transforming to a standardized scale; regardless of transformation, higher domain scores represent better quality of life.

Physical function will be assessed using the physical function section of the Multidimensional Health Assessment Questionnaire (MDHAQ) in both the older adults with RA and frailty and their informal caregivers. The MDHAQ physical function scale comprises 10 activities of daily living, each scored on a 0–3 scale (from no difficulty to unable to do), and will be summarized as a total score (commonly reported as a 0–10 raw sum or transformed to a 0–3 metric), with higher scores indicating greater functional limitation [31,32]. In patients with rheumatic disease, MDHAQ function is widely used as a pragmatic, low-burden measure for routine care and research [33,34]. For informal caregivers, MDHAQ function is used here as a generic self-reported indicator of everyday functional capacity rather than a disease-specific disability measure; a key limitation is that measurement properties and interpretability (including responsiveness and clinically meaningful thresholds) are less well-established in caregiver populations, and floor/ceiling effects may be more pronounced if many caregivers have minimal functional limitations [35,36]. Therefore, we will interpret caregiver MDHAQ function scores descriptively, and will report score distributions and the proportion at the floor/ceiling alongside data completeness at baseline and follow-up; where helpful, we will contextualize patterns using available population-based functional disability benchmarks from HAQ-type instruments [37].

Questionnaire data will be collected using REDCap [38]. Participants will complete questionnaires electronically, and responses will be entered and stored directly within the REDCap platform to support standardized, secure data capture and management.

Qualitative evaluation

A purposive sample of caregivers, based on age sex and relation to the frail older adult, will be invited for semi-structured interviews after completing the intervention to explore perceived relevance, benefits, burdens, and suggestions for improvement. A subset of older adults who were participated in consultations may also be interviewed to capture dyadic perspectives. The healthcare professional delivering the intervention will interview to explore implementation barriers, facilitators, and resource implications. Data will be analyzed using thematic analysis, guided by the INSPIRE logic model (REF) and feasibility domains.

Table 1. Schedule of enrolment, interventions, and assessments

Study period	Enrolment	Baseline	Post-allocation (intervention period)	Close-out
Timepoint	Screening - during recruitment window	Week 0	Weeks 0-12	Week 12
ENROLMENT				
Identification via routine clinic pathway (DANBIO pop-up for RA patients with MDHAQ $\geq$ 1.0)	X			
Telephone information to patient and frailty screening	X			
Clinical Frailty Scale (CFS) for older adult eligibility	X			
Caregiver contact and study information	X			
Caregiver Burden Scale (CBS) eligibility screening (mean > 1.99)	X			
Informed consent (informal caregiver and older adult with RA)	X			
INTERVENTION				
INSPIRE delivery (tailored toolbox; validation/goal-setting/navigation support)			X	
INSPIRE brief follow-up contact (progress review/adjustment)			X	
INSPIRE final consultation (review/ongoing plan)			X	
FEASIBILITY OUTCOMES				

Recruitment metrics (screened/eligible/approached/consented; reasons)	X			
Retention (follow-up completion; withdrawals and reasons)				X
Intervention deliverability (sessions completed; mode; duration)			X	X
Fidelity and tailoring documentation (core components delivered; toolbox elements selected)			X	X
Data completeness (item/scale completeness for questionnaires)		X		X
Post-intervention acceptability				X
Harms/distress monitoring and signposting/referral if needed		X	X	X
CAREGIVER AND PATIENT-REPORTED OUTCOMES (EXPLORATORY)				
Caregiver burden (CBS)		X		X
Caregiver quality of life (WHOQOL-BREF)		X		X
Older adult quality of life (WHOQOL-BREF)		X		X
Caregiver physical function (MDHAQ)		X		
QUALITATIVE EVALUATION (POST-INTERVENTION)				
Informal caregiver semi-structured interview (purposive sample)				X
Older adult semi-structured interview (subset; if involved in consultations)				X
Delivering professional semi-structured interview				X

CBS = Caregiver Burden Scale; CFS = Clinical Frailty Scale; RA = rheumatoid arthritis; T0 = baseline; T1 = 12-week follow-up; WHOQOL-BREF = World Health Organization Quality of Life – BREF.

Analysis

Statistical methods

Analyses will be descriptive. Recruitment, retention, completeness, and deliverability will be summarized with proportions and appropriate uncertainty (e.g., confidence intervals where useful). CBS and WHOQOL-BREF outcomes will be summarized at baseline and follow-up, and exploratory pre–post changes will be presented with effect size estimates and confidence intervals without formal hypothesis testing.

Qualitative analysis´

Qualitative findings will be analyzed thematically and integrated with quantitative feasibility findings to inform refinement of both the intervention and trial procedures.

Data management and confidentiality

Data will be handled in accordance with GDPR and Danish data protection requirements, stored securely with access control, and reported in anonymized form. Linkage keys will be stored separately from study datasets.

Monitoring and harms

The study is low risk and involves no invasive procedures. Some participants may experience emotional discomfort when discussing caregiving challenges; participants may pause or stop at any time. Delivering professionals will follow pre-defined pathways for signposting or referral if distress is identified.

Ethics

In accordance with Danish legislation, this study was assessed as not requiring approval by the Regional Scientific Ethical Committee and was registered accordingly (registration no. F-25068393). The project was accepted and registered by the Danish Data Protection Agency (journal number:XXXXX). The principles of the Declaration of Helsinki will be followed.

Before signing informed consent, the participants will receive written and oral communication. While orally communicating information about the study, it will be determined whether the patient fulfills the criteria for participation. The patients will be screened for eligibility according to the inclusion and exclusion criteria. Following the meeting, they are offered 3 days to consider their decision. Only after signing the informed consent form, they are enrolled in the trial.

Patient and public involvement

INSPIRE was developed through a stakeholder-informed co-creation process involving older adults with RA and frailty, informal caregivers, caregiver mentors, healthcare professionals and social care stakeholders, drawing on co-creation principles and prototyping guidance [39]. In line with EULAR recommendations on involving patient research partners in rheumatology research, patient partners contributed during the development work, and involvement processes will be evaluated using the PEIRS-22 measure of meaningful engagement [40]. Reporting of patient and public involvement in outputs from the feasibility study will follow GRIPP2 guidance where applicable [41].

Dissemination

Results will be disseminated through a least one peer-reviewed publication, conference presentations, and accessible summaries shared with participants, patient organizations, and clinical and municipal stakeholders, with the aim of informing refinement and planning of a subsequent effectiveness evaluation.

Expected findings

This feasibility study is expected to show whether INSPIRE can be delivered as intended within routine rheumatology care and whether informal caregivers perceive the intervention as relevant and acceptable. We anticipate that the planned recruitment pathway, using routine patient-reported outcomes and targeted screening for frailty followed by identification of an informal caregiver, will be practicable but may require refinement to optimize reach. In particular, we expect that not all eligible older adults will be willing or able to nominate an informal caregiver, and that caregiver consent rates may vary depending on perceived time demands, relationship dynamics, and current caregiving strain.

Regarding deliverability, we expect that the three consultations over approximately twelve weeks will be manageable within clinical workflows when supported by structured session notes and a defined toolbox. We anticipate that tailoring will be central to acceptability, with different informal caregivers

drawing on different toolbox elements depending on whether their burden is primarily related to emotional distress, practical strain, social isolation, or challenges navigating municipal and healthcare services. Fidelity documentation is expected to demonstrate that core components (recognition/validation, goal-setting, and navigation support) can be delivered consistently while allowing individualized emphasis.

For study procedures, we expect acceptable retention and questionnaire completeness at 12 weeks, although some missing data may occur among informal caregivers experiencing high strain or competing responsibilities. While the study is not designed to test effectiveness, exploratory pre–post summaries are expected to indicate whether the selected outcome measures are responsive and feasible in this population. We anticipate potential signals in the expected direction, particularly reduced caregiver burden and improved aspects of quality of life, alongside qualitative accounts describing increased validation, clearer pathways for support, and improved confidence in managing and coordinating care. Together, the quantitative feasibility metrics and qualitative feedback will inform whether progression criteria are met and what amendments are needed before a definitive evaluation.

Study limitations

As a single-arm feasibility study with a small sample size, the study cannot determine intervention effectiveness, and any observed changes in informal caregiver burden or quality of life must be interpreted cautiously because they may reflect regression to the mean, natural variation, or contextual influences rather than intervention impact. The limited sample will also restrict precision in estimating feasibility parameters and will reduce the ability to explore differences across caregiver subgroups or across levels of frailty.

The study is conducted within specific clinical and regional contexts, which may limit transferability to other healthcare systems and service configurations, particularly where access to municipal supports, or rheumatology follow-up differs. Recruitment may be subject to selection effects because participation depends on older adults indicating interest, being reachable for screening, and nominating an informal caregiver, and because caregivers must report at least moderate burden to be eligible; consequently, findings may not represent informal caregivers with low burden, those reluctant to identify as caregivers, or those in strained relationships where participation is less likely. The fixed recruitment

window may further constrain representativeness by capturing a limited period of clinic flow and staffing conditions.

Finally, feasibility and acceptability outcomes rely largely on self-report questionnaires and interviews, which may be influenced by social desirability and differing interpretations of burden and quality-of-life items. The 12-week follow-up may be sufficient to assess short-term feasibility and perceived usefulness but may not capture sustainability of benefits, longer-term service navigation outcomes, or delayed changes in caregiver strain. These limitations are acceptable for a feasibility study and will be used to guide refinement of recruitment procedures, outcome selection, follow-up timing, and the design of a future definitive evaluation.

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